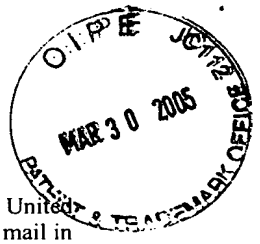


Docket No: 25401-26

PATENT

CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Attn: Mail Stop Appeal Brief-Patents; Commissioner for Patents; P.O. Box 1450; Alexandria, VA 22313-1450 on March 28, 2005.

Bonnie S. Heroux

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Ib Mendel-Hartvig et al	:	Paper No.:
Serial No.:	09/582,808	:	Group Art Unit: 1641
Filed:	October 16, 2000	:	Examiner: G. Counts

For: **ANALYTICAL METHOD USING PARTICLES AND TEST KIT FOR PERFORMING THE METHOD**

REPLY BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The present Reply Brief is submitted in response to the Examiner's Answer dated January 27, 2005. Particularly, the present Reply Brief responds to issues raised in the Examiner's Answer.

I. Batz et al Provide No Motivation for the Asserted Combination

At pages 12-14 of the Examiner's Answer, the Examiner asserted that Batz et al teach that the hydrophilic latex particles provide for a diagnostic agent which has covalently bound biological and/or immunological active substances and that immunologically active substances which are not bound covalently can be dissolved off during the measurement in the course of a diagnostic test, and the Examiner concludes therefore that Batz et al teach the advantages of hydrophilic particles in diagnostic assays. The Examiner continues that while Appellants have recognized another advantage which would flow naturally from following

the suggestion of the prior art, such cannot be the basis for patentability when the differences would otherwise be obvious.

Appellants submit however that the Examiner has, in hindsight, taken selected portions of the teachings of Batz et al which support the Examiner's position, to the exclusion of the remaining parts of Batz et al which are necessary to the full apprehension of what Batz et al fairly suggest to one of ordinary skill in the art. *In re Wesslau*, 147 U.S.P.Q. 391, 393 (C.C.P.A. 1965); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). On the other hand, when the teachings of Batz et al are properly viewed in their entirety, one of ordinary skill in the art would not be motivated to combine the teachings of Batz et al with Charlton et al to result in the method and test kit as respectively defined in claims 42 and 63.

More particularly, Batz et al note four disadvantages of prior art latex particles which impair their use as carriers for immunologically-active substances and prevent their use in *continuous solution measurement systems* (column 1, lines 59-60), namely 1) serum components bind nonspecifically, 2) immunologically-active substances which are only bound adsorptively but not covalently can be dissolved off during the measurement in the course of a diagnostic test, 3) emulsifiers or stabilizers can destroy the structure and thus the activity of biologically-active proteins, and 4) latex suspension coagulation and destabilization by centrifuging to remove stabilizing tensides (column 1, line 54-column 2, line 10). On the other hand, Batz et al teach that their latex particles are able to covalently bind biologically and/or immunologically-active substances which do not impair the structure and thus the activity of the biologically-active proteins, the stabilization of which is not destroyed by centrifuging and which coagulate and can subsequently easily be resuspended again (column 2, line 59-column 3, line 2). One skilled in the art would have recognized these advantages for the solution measurement systems of Batz et al.

In view of Batz et al's teachings of latex particles for continuous solution measurements, Appellants submit that one of ordinary skill in the art would have no motivation for employing the latex particles of Batz et al, designed for continuous solution measurements, in the matrix flow path of the Charlton et al device. Not only do Appellants find no teaching or suggestion by Batz et al that their latex particles are suitable for absorption to a second solid support or flow matrix of the type taught by Charlton et al, one of ordinary skill in the art would recognize that the objectives of Batz et al for a solution assay, to prevent impairment of reactants, may well be counter to the constraints of a flow path device as taught by Charlton et al.

When the teachings of Batz et al are viewed in their entirety, one of ordinary skill in the art would have had no motivation, absent the teachings of the present application, for combining the teachings of Batz et al relating to latex particles for a solution assay to the matrix flow path device of Charlton et al. Accordingly, Batz et al do not resolve the deficiencies of Charlton et al and the combination of Charlton et al and Batz et al does not render the presently claimed methods and test kits obvious under 35 U.S.C. §103.

II. Brown et al Fail To Teach the Claim Limitations

In response to Appellant's arguments that Brown et al fail to teach or suggest the limitation of claims 42 and 63 that the particulars have a diameter smaller than a smallest inner dimension of the flow channels of the flow matrix, the Examiner's Answer states that Brown et al specifically teach that the average diameter of the particles is less than the average pore size of the matrix (page 14). However, the Examine fails to indicate how the teaching of Brown et al, that the average diameter of the particles is less than the average pore size of the matrix, teaches that the particles must have a diameter smaller than a smallest inner dimension of the flow channels of the flow matrix, as required by claims 42 and 63. Perhaps recognizing this deficiency, the Examiner's Answer then contends that the optimum

dimension and diameter of the flow channels and particle size can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art (page 14). However, as Appellants have previously noted, Brown et al provide no teaching or suggestion as to any importance of particle size, and to the contrary, Brown et al disclose that the size of the particles is "not critical" (column 9, lines 11-17). It is well settled that it is not obvious to optimize a parameter not recognized as a result-effective variable, *In re Antonine*, 195 U.S.P.Q. 6 (C.C.P.A. 1977), and the Examiner cannot merely disregard claim limitations as obvious when these limitations are neither taught nor suggested in the prior art of record.

III. Dafforn et al Fails to Disclose the Limitations of Claims 58 and 79

At page 17, the Examiner's Answer asserts that Dafforn et al teach that the Reactant* is predeposited in the matrix upstream of sample application, referring to column 19, line 15-column 20, line 22 of Dafforn et al. Appellants have again reviewed the teachings of Dafforn et al at column 19, line 15-column 20, line 22 and find no teaching or suggestion therein of the limitations of claims 58 and 79, particularly that the analytically detectable Reactant* is predeposited in the matrix upstream of a sample application site. While Dafforn et al generally disclose that specific binding pair members (sbp members) and members of the signal producing system can be bound to bibulous material by absorption or covalent bonding, and that such binding can be non-diffusive or diffusive (column 19, lines 15-20), Appellants find no teaching or suggestion that an analytically detectable reactant, such as Reactant*, is predeposited in the flow matrix *upstream of a sample application site.* Thus, Dafforn et al do not resolve the deficiencies of Charlton et al, Batz et al and Brown et al with respect to claims 58 and 79, whereby these claims are independently patentable.

IV. Improper Combination of Prior Art

Throughout the Examiner's Answer, the Examiner indicates which portions of the respective cited references are relied upon and which portions of the respective references are

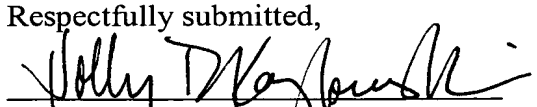
not relied upon in making the rejections. For example, the Examiner apparently disregards the fact that Bennich et al do not teach or suggest a flow matrix and rather conduct a solution assay, as the Examiner indicates the Examiner has relied upon Bennich et al only for teaching immobilization of allergens used in an assay. However, the teachings of Bennich et al directed to solution assays are relevant in what the full teachings of Bennich et al suggest to one of ordinary skill in the art. Similarly, the Examiner apparently disregards the failure of Devlin et al to teach or suggestion a flow matrix method or device. However, this deficiency in the Devlin et al teachings is relevant to the full appreciation of what Devlin et al fairly suggest to one of ordinary skill in the art.

It is impermissible within the framework of Section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art, *In Wesslau, supra.*; *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., supra.* Moreover, the Examiner cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention; rather, the Examiner has the burden to show some teaching or suggestion in the references to support their use in the particular claimed combination, *Smith-Kline Diagnostics, Inc. v. Helena Laboratories Corp., 8 U.S.P.Q. 2d 1468, 1475 (Fed. Cir. 1988).* Appellants submit that when the full teachings of each of the cited references are considered, one of ordinary skill in the art would have found no motivation to combine their teachings along the lines asserted by the Examiner to result in the presently claimed methods and test kits. Accordingly, the rejections under 35 U.S.C. §103 should be reversed.

V. Conclusion

For the reasons set forth in detail in Appellants' Appeal Brief and as further demonstrated above, the rejections under 35 U.S.C. §103 are deficient and should therefore be reversed. Favorable action by the Board is respectfully requested.

Respectfully submitted,



Holly D. Kozlowski, Reg. No. 30,468
Dinsmore & Shohl LLP
1900 Chemed Center
255 East Fifth Street
Cincinnati, Ohio 45202
(513) 977-8568

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